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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

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12/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/707,685	PALMAZ ET AL.	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2009 and 01 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53 and 67-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53 and 67-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 1, 2009 and August 21, 2009 has been entered.

Response to Arguments

Applicant's arguments filed August 21, 2009 and September 1, 2009 have been fully considered but they are not persuasive. It is also noted that although applicants arguments (exhibit a and b being included in applicants arguments) have been considered carefully by the examiner, the publications provided in exhibits a and b in order to be officially of record and officially considered as prior art should be provided in an information disclosure statement.

The applicant has argued that Whitcher (US 2003/0018381 A1) does not define the terms nanocrystalline and monocrystalline, seemingly arguing that these are not "crystalline" as claimed. The examiner disagrees. Whitcher clearly discloses production of a crystalline structure (which is the extent as applicant has defined it in their specification), discloses that monocrystalline and nanocrystalline are examples of crystalline structures, see P0011 "have a crystallographic structure…include amorphous, nanocrystalline and monocrystalline", P0038 "the crystalline structure of the metallic medial article", P0040 "form the same crystalline

structure, i.e., monocrystalline", P0043 "deposited material forms a crystalline structure", P0048 "formed to have a range of crystalline morphologies, including a monocrystalline or a nanocrystalline morphology", claim 1, "amorphous, nanocrystalline, crystalline, and monocrystalline". The deposited film of Whitcher is clearly supported to be crystalline in some embodiments.

The applicant has also argued the minimizing precipitates does not equate to minimizing impurities and precisely controlling the microstructure (as disclosed by Whitcher, P0028, P0040, P0062). Although they may not equate to one another, it is the examiner opinion that microstructure or impurities (as disclosed by Whitcher) encompasses precipitates since applicants themselves group together precipitates with other properties similarly disclosed by Whitcher, under the definition "material properties", see pg.10 of applicants specification.

The applicant further argues that precipitates are a product of increased thermal conditions (annealing) and provides Exhibit B which briefly discusses the formation of precipitates under specific annealing temperatures. Whitcher however, discloses deposition methods that *do not require* the annealing high temperature processes, thus would not form precipitates in the first place. Exhibit B when discussing formation of precipitates, occurs under annealing only and not under deposition processes as are claimed by applicant and disclosed by Whitcher. As Exhibit B's processing techniques differ than that discloses by Whitcher, it is inaccurate to assume Whitcher's films contain precipitates.

It is also noted that applicants specification admits that the material properties (including precipitates) "are *achieved* by fabricating a stent by the same metal deposition methodologies as are *used and standard* in the microelectronics and nano-fabrication vacuum coating arts", pg.11,

lines 10-15. These "used and standard" deposition methods are the same methods disclosed and referred to in Whitcher. Thus it seems inherent since the same methods are used, the same material properties (including minimized precipitates) will be *achieved* by Whitcher.

Further, the applicant admits that the vapor/vacuum deposition processes of nickel titanium eliminates the need to control precipitates, since no precipitates exist in the deposited film (see pg.14, lines 19-30). "Vapor deposition of the inventive endoluminal stent..significantly reduces or virtually eliminates inter- and intra-granular precipitates in the bulk material. It is common practice in the nickel-titanium endoluminal device industry to control transition temperatures and resulting mechanical properties by altering local granular nickel-titanium ratios by *precipitation regimens*. In the present invention, *the need to control precipitates for mechanical properties is eliminated*. Where nickel-titanium is employed as the stent-forming metal in the present invention, local nickel-titanium ratios will be the same or virtually identical to the nickel-titanium ratios in the bulk material, while still allowing for optimal morphology and *elimination the need for employing precipitation heat treatment*." This disclosure admits that by using standard vapor/vacuum deposition methods of nickel titanium, there is not need to anneal (heat treat) the finished product to remove precipitates, since no precipitates are formed during the deposition process. Again, since Whitcher uses the same standard deposition methods disclosed by applicant, and does not anneal/heat treat, no precipitates exist in the Whitcher's stent, thus Whitcher is inherently minimizing the formation of precipitates just as applicant is.

The applicant also argues that the specification incorporates by reference 09/443,929 (US 6,379,383) which provides one working example of process conditions that are different than that of Whitcher, thus Whitcher's material properties produced is not inherent. The

examiner disagrees. The process conditions disclosed in the incorporated application are only one example of process conditions and they are not disclosed to reduce precipitates nor are they disclosed to be used with nickel titanium. One may not assume that the same process parameters would be used with a different material (the claimed nickel titanium) and to reduce precipitates. Also, applicant's specification discloses that standard deposition methods produce the material properties desired and does not limit the deposition to any particular process parameters for reducing precipitates.

Some of applicants previously arguments (in the appeal brief filed April 30, 2007) addressed previously are supplied below as they are applicable to the examiners interpretation of the claimed subject matter and position on the Whitcher reference.

The applicant has argued that "selected to minimize" is not analogous to preselected or predetermined. This argument made by the examiner was in the examiners "response to arguments" section of the final office action, not part of the actual rejection however the examiners response in that action is still believed to be the examiners opinion and it cited below since it was referred to in the appeal brief:

"The applicant has argued that Whitcher does not disclose a process condition selected to minimize formation of intra and inter granular precipitates, and that this property is not inherently controlled in Whitcher. The examiner disagrees. Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of

the microstructure. Further, *process conditions* are known in the art to comprise temperature, pressure and deposition rate. For any vacuum deposition process, a user must *select* a temperature, pressure, and deposition rate. Therefore, the user has completed the method *under process conditions selected*. What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users *selection* of the *condition*). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeals Federal Circuit."

The applicant has further argued that Whitcher does not disclose:

1) the deposited film is crystalline and

2) that precipitate formation has been controlled

The examiner disagrees for the below reasons:

1) Whitcher discloses a film that may be deposited in various different forms of crystallinity. It may be deposited as amorphous (low or no crystallinity) and also monocrystalline and nanocrystalline, both crystalline by name. See P0011, "The medical devices also have a *crystallographic structure* that is ***produced by*** the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, *nanocrystalline, and monocrystalline* structures." Emphasis added. Whitcher clearly discloses crystalline films (nanocrystalline and monocrystalline) that are as-deposited ("structure ***produced by*** the vapor deposition"-not ***produced by*** post treatment). Whitcher also discloses that the microstructure (analogous to crystallinity-how crystalline a material is) is controlled by the vapor deposition technique, see P0028. Whitcher also discloses vacuum deposition processes such as

ion beam deposition densifies the product, filtering out impurities and purifying the crystal structure of the product, making more crystalline, see P0037-P0038. Whitcher discloses depositing an as-deposited crystalline film (no post-treatment, is deposited in a crystalline state), see P0040 by ion beam, second part of P0043, end of P0048, P0061, and pg.7, claim 1. Although it is true that Whitcher does disclose an embodiment wherein an amorphorous film is deposited and then post-treated to make crystalline (thus not "as-deposited", first part of P0041) this is only one embodiment disclosed by Whitcher and not the embodiment referred to by the examiner in the rejection.

2) Whitcher discloses precisely controlling the material properties and microstructure of the material (by selection of process conditions), and therefore inherently the precipitates are controlled since they are a component of the microstructure, see P0011, P0028, P0037, P0038, P0042, P0062 and above rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 and 67-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited previously). Referring to claims 39 and 67, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second

structural elements (see interconnected struts in fig.2 or 3 for example), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the applicant, are disclosed by Whitcher, see P0034-P0037) a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, rate [0035, 0036, 0037]) *selected* (a temp, pressure and rate is disclosed to be selected) to minimize the formation of chemical and intra and inter-granular precipitates in the bulk material of a deposited tubular unpatterned metal crystalline film (115; Whitcher discloses deposition of either an amorphous OR *a crystalline film*, see P0038-P0040, P0043, P0049, P0061, example 1), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the applicant's specification as one of the many "material properties" that are collectively controlled by deposition, see pg.10, lines 12-16. The applicant's specification discloses that the collection of material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates* and other material properties. Although Whitcher does not explicitly recite granular precipitates, Whitcher does

disclose use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, and discloses such processes control material properties (P0011, P0028), inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline.

Also, applicant has claimed "process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is and how it should be examined. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition, since crystalline, would have no precipitates.

Referring to claims 40 and 68, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [P0053].

Referring to claims 41-45 and 69-72, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [P0034, P0035, P0036, P0037].

Referring to claims 45 and 73, Whitcher discloses a deposition rate no less than 20 nm/sec ([P0035], > 0.05 mm/min).

Referring to claims 46 and 74, Whitcher discloses rotation of the substrate during deposition ([P0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [P0034, P0035, P0036, P0037] nickel and titanium [P0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [P0066, 55.9 is not less than 51.5], table 1, the deposition occurring under process conditions selected to minimize the formation of granular precipitates in the bulk material of a deposited tubular unpatterned crystalline film (P0038-P0040, P0043, P0049, P0061, example 1), and removing the stent from the substrate [0051, 0052, 0053].

Referring back to the limitation, process condition "selected to minimize" granular precipitates, granular precipitates are categorized in the applicant's specification as "material properties" and are part of the microstructure see pg.10, lines 12-16. The applicant's specification discloses that the material properties, including the granular precipitates, are controlled or minimized by the actual deposition process, see pg.11, lines 11-15; pg.11 line 30-pg.12, line 2; pg.12, lines 11-13; pg.14, lines 1-12, 19-21. That is, Applicant's disclosure points simply to a vacuum deposition process (sputtering and ion-beam evaporation; pg.11, lines 11-24) as *the means for minimizing precipitates*. Whitcher discloses use of the same vacuum deposition processes (sputtering, ion beam deposition, etc., P0034-P0037) and the use of the same materials used by the applicant (P0062) therefore, inherently Whitcher is controlling and minimizing material properties such as granular precipitates just as much as the applicants are.

Further, Whitcher specifically discloses *accurately and precisely controlling* the composition and microcrystal structure to have the desired mechanical properties [P0011, 0028, 0038, 0042, 0043], therefore, inherently the granular precipitates are controlled, since granular

precipitates are an element of a materials microstructure and the material's mechanical properties, the microstructure and properties which are disclosed to be controlled.

Additionally, Whitcher discloses *selection* of a process *condition*. Whitcher discloses selection of a temperature, pressure, and rate during deposition, therefore, inherently the precipitates are being controlled, since amount and size of the granular precipitates are dependent upon temp, pressure, and rate (general process conditions of vacuum deposition, which applicant has disclosed to be the method of minimizing precipitates), and upon selection of these conditions, one has *controlled* the crystal structure outcome of the metal, hence controlled how much formation of precipitates has occurred. Because Whitcher has disclosed a temperature, pressure, and rate, hence the material properties are preselected and are being controlled by the *selection*. Also, every metal has a specific granular makeup, including precipitates, and just by the user *selecting* a specific material to be deposited, the user is *controlling* the grain size, grain phase, granular precipitates, composition, and binding sites etc.

Further, applicant noted in their previous arguments, inherently precipitates are formed in all post treatments such as annealing. Since some of Whitcher's methods disclose depositing a crystalline film, without the use of annealing process, no precipitates would be formed in the first place, thus are already minimized, since no annealing has taken place and the deposited film is crystalline. As applicant's specification points out, pg.14, lines 19-30, if deposition processes are used for nickel titanium alloys, there is no need to control the precipitates as there are not any in the deposited film. No annealing is required. The specification also points out that it is the vapor deposition process that significantly reduces or virtually eliminates the precipitates. Thus if it is the deposition process alone that reduces the presence of precipitates, Whitcher inherently

reduces the presence of precipitates in the performance of the same standard deposition methods disclosed by applicant.

Also, applicant has claimed "process conditions selected to *minimize formation* of chemical and intra and inter-granular precipitates", however they have not claimed to what extent (numerical value) such properties are minimized to. No numerical amount has been assigned to "minimized". It is vague and arbitrary what amount "minimize" is. It is unclear how to interpret such a word, with no exact value. As best as can be interpreted, Whitcher is believed to have "minimized" formation of precipitates, since the disclosed film may be crystalline upon deposition.

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Conclusion

This is a RCE of applicant's earlier Application No. 09/707,685. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

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